AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO COMMITTEE PRINT FOR SUBTITLE E RELATING TO DRUG PRICING

Offered by M .

Add at the end of part 2 the following new section:

1 SEC. 30513. CERTIFICATION REQUIREMENT.

- 2 Notwithstanding any preceding provision of, or
- 3 amendment made by, this part, no such provision or
- 4 amendment shall apply before the date on which the Sec-
- 5 retary of Health and Human Services submits to Congress
- 6 a certification that the amendments made by this part will
- 7 not result in increased launch prices for new prescription
- 8 drugs in the 6 protected classes. For purposes of the pre-
- 9 ceding sentence, the "6 protected classes" are the pro-
- 10 tected classes listed by the Centers for Medicare & Med-
- 11 icaid Services in the Medicare Prescription Drug Benefit
- 12 Manual Chapter 6—Part D Drugs and Formulary Re-
- 13 quirements, § 30.2.5 (2016).

